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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/392,934	10/28/1996	RICHARD S. SMITH	01-3033	9871

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EXAMINER	
SCHWADRON, RONALD B	
ART UNIT	PAPER NUMBER
1644	47

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 08/392,934	Applicant(s) Smith et al.
	Examiner Ron Schwadron	Art Unit 1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Dec 18, 2001* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *31, 34, and 37-52* is/are pending in the application.

4a) Of the above, claim(s) *45-50* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *31, 34, 37-44, 51, and 52* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/18/2001 has been entered.

2. Claims 31,34,37-44,51,52 are under consideration. Claim 41 has been amended.

3. Regarding applicants comments about an IDS filed 12/18/2001, the IDS and copies of the related references was not received.

4. Claims 31,34,37-44,51,52 are objected to because of the following informalities. Applicant needs to amend the claims to recite the SEQ. ID. no. where a sequence is recited in said claims. See 37 CFR 1.821 (d). Appropriate correction is required.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 31 and 42 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for the reasons elaborated in the previous Office Action. Applicants arguments have been considered and deemed not persuasive.

The specification does not disclose how to use the instant invention for the therapy of EBV related disease in vivo in humans. The claimed pharmaceutical composition is disclosed in the specification as used for the treatment of EBV related disease in vivo in humans. Applicant has not enabled the breadth of the claimed invention in view of the teachings of the specification because the use for the instant invention disclosed in the specification is the in vivo treatment of disease in humans. The state of the art is such

that is unpredictable in the absence of appropriate data as to how the instant invention could be used for the treatment of disease in vivo in humans. The specification provides no working examples indicating that the method of the instant invention can be used for the treatment of human disease. Jackman et al. teaches that there is currently no available vaccine for treatment of EBV related disease in humans (see abstract). Jackman et al. teach that in order to establish whether an EBV related protein would even be tested to determine that said protein could be used to treat EBV related disease in humans, that it was necessary to obtain appropriate in vivo data in an appropriate in vivo preclinical model such as cottontop tamarins (eg. see page 660, second column). The specification supplies no in vivo data in any animal model indicating that the claimed invention can be used to treat EBV related disease in humans. It appears that undue experimentation would be required of one skilled in the art to practice the instant invention using the teaching of the specification. See In re Wands 8 USPQ2d 1400(CAFC 1988).

Jackman et al. teaches that there is currently no available vaccine for treatment of EBV related disease in humans (see abstract). Jackman et al. teach that in order to establish whether an EBV related protein would even be tested to determine that said protein could be used to treat EBV related disease in humans, that it was necessary to obtain appropriate in vivo data in an appropriate in vivo preclinical model such as cottontop tamarins (eg. see page 660, second column). Jackman et al. teach that in order to even be considered as a potential vaccine candidate a particular vaccine must be capable of eliciting a particular titer of antibody in vivo (eg. see page 666, second column, last paragraph). Furthermore, Jackman et al. indicate that even based on the in vivo data disclose in their publication that, "It remains to be seen whether MSTOP gp350 will be capable of eliciting a sufficient immune response to protect against EBV related diseases in humans.". The instant discloses no in vivo data in any model showing the ability of the claimed peptides to treat human disease.

Regarding applicants comments, the Patent Office takes the position that the recitation of an intended use (eg. pharmaceutical composition) in a composition claim carries patentable weight regarding issues of enablement. A pharmaceutical composition is used for the treatment of human disease. Regarding issues of enablement, a pharmaceutical composition is evaluated for its intended use (eg. treatment of human disease). The use of the claimed invention to make monoclonal antibodies is irrelevant to

the issue under consideration because the claimed invention is drawn to a pharmaceutical composition, wherein said composition is used to treat human disease.

7. Claims 41-44,51,52 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons elaborated in the previous Office Action.

There is no support in the specification as originally filed for the polypeptide of claim 41 or 52. Applicant has indicated that said peptide finds support in the specification, pages 8 and 9. The specification, pages 8 and 9 discloses polymers of the claimed peptides. However, there is no disclosure of the identity of said polymers or that said polymers have the particular features recited in claim 41. For example, there is no disclosure in the specification of polymers that contain 2 or 3 or 4 of the particular peptides recited in claim 41 or 52. There is no disclosure in the specification that a particular amount of any particular peptide is used in combination with a particular amount of any other peptide in order to produce a polymer. There is also no support in the specification as originally filed for the recitation of "randomly ordered" in claim 52. There is no written description of the scope of the claimed invention in the specification as originally filed (eg. the claimed invention constitutes new matter).

8. Claim 44 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 44 recites the limitation "wherein o is 0 and p is 0" . There is no antecedent basis for this limitation in claim 41.

9. Regarding the application of prior art, for the same reasons that the instant invention constitutes new matter, the claimed inventions are not entitled to priority to the parent applications to which the instant invention claims priority.

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 41-44,51 stand rejected under 35 U.S.C. 102(b) as being anticipated by Smith et al. WO 94/06470 for the reasons elaborated in the previous Office Action. Applicants arguments have been considered and deemed not persuasive.

Smith et al. teach the claimed invention (see claims 1,31,34,36).

Regarding applicants comments, for the same reasons that the instant invention constitutes new matter, the claimed inventions are not entitled to priority to the parent applications to which the instant invention claims priority. Regarding applicants comments, while WO 94/06470 does not disclose the scope of the claimed inventions (eg. the particular multimers recited in the claims) it does the particular monomers encompassed by the claimed invention.

12. Claims 41,44 stand rejected under 35 U.S.C. 102(b) as being anticipated by Pothen et al. for the reasons elaborated in the previous Office Action. Applicants arguments have been considered and deemed not persuasive.

Pothen et al. teach the claimed peptide (see Table 1).

Regarding applicants comments, for the same reasons that the instant invention constitutes new matter, the claimed inventions are not entitled to priority to the parent applications to which the instant invention claims priority. Regarding applicants comments, while WO 94/06470 does not disclose the scope of the claimed inventions (eg. the particular multimers recited in the claims) it does the particular monomers encompassed by the claimed invention.

13. Claims 31,34,37-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Pearson et al.

Regarding claim 37, the term "polypeptide consisting of an amino acid sequence having the formula" is interpreted as open language equivalent to polypeptide comprising. Pearson et al. teach EBV p17 (the intact protein which contains the sequence recited in the claims)(see Figure 2) and that said peptide binds human sera containing antiEBV antibodies (see page 156, second column). Said peptide would have been in a container. Pearson et al. teach said peptide in a pharmacological carrier (see page 153, first column).

14. No claim is allowed.

15. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 308-4242.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP 1800 1600

Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644